(FORM PTO-1390 (REV 10/95))

U. S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER: CERA-233

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR): 09/937722

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/EP00/03240	11 April 2000	11 April 1999

TITLE OF INVENTION
MEDICAL INSTRUMENTS

APPLICANT(S) FOR DO/EO/US
Ralf-Peter FRANKLE, Michael FRIPAN, Wolfgang BURGER, Herbert RICHTER

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ■ This is the FIRST submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.
3. ■ This express request to begin national examination procedures (35 U.S.C. 371(f) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(l).
4. ☐ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ■ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ■ is transmitted herewith (required only if not transmitted by the International Bureau.)
   b. ■ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ■ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ■ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. ■ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ▫ Assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A FIRST preliminary amendment.
    ☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☐ Other items or information:
17. ▪ The following fees are submitted:
18. ☐ Other: A copy of International Search Report with a translation into English

BASIC NATIONAL FEE (37 CFR 1.492(A)(1) - (5)):		
Search Report has been prepared by the EPO or JPO $860.00		
International preliminary examination fee paid to USPTO (37 CFR 1.482) $690.00		
No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)) . . . $710.00		
Neither International preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO $1000.00		
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) $100.00		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$860.00	
Surcharge of $130.00 for furnishing the oath or declaration later than ☐ 20 ■ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$130.00	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims		0	x $18.00	$	
Independent		0	x $80.00	$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ $250.00	$	
	TOTAL OF ABOVE CALCULATIONS =			$990.00	
Reduction of ½ for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).				$	
SUBTOTAL =				$990.00	
Processing fee of $130.00 for furnishing the English translation later than ☐ 20 ■ 30 months from the earliest claimed priority date (37 CFR 1.492(f)). +				$130.00	
TOTAL NATIONAL FEE =				$1,120.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). $40.00 per property+				$	
TOTAL FEES ENCLOSED =				$1,120.00	
				Amount to be: refunded	$
				charged	$

a. ■ A check in the amount of $1120.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. 50-0624 in the amount of $____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ■ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 50-0624. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:
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SIGNATURE

James R. Crawford
NAME

Date: September 28, 2001

39,155
REGISTRATION NUMBER

EXPRESS MAIL NO.EL 829643459 US

CERA-233

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	:	FRANKE, et al.
Serial No.	:	09/937,722
Filing Date	:	September 28, 2001
For	:	MEDICAL INSTRUMENTS

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

February 7, 2002

PRELIMINARY AMENDMENT

Sir:

Prior to examination please amend the application as follows:

IN THE CLAIMS

Cancel claims 1-29, without prejudice and add the following claims:

30. A medical/surgical instrument comprising biocompatible bioinert material.

31. A medical/surgical instrument characterized in that it is coated with biocompatible bioinert material.

32. The medical/surgical instrument according to claim 30, wherein the biocompatible bioinert material is high-strength technical ceramic.

33. The medical/surgical instrument according to claim 30, wherein the biocompatible bioinert material is a ceramic comprising at least one of an aluminum oxide, zirconium oxide and silicon nitride.

34. A medical/surgical instrument according to claim 30, wherein the biocompatible bioinert material is a YTZP or ZTPA ceramic.

35. A medical/surgical instrument according to claim 30, wherein it is formed as scalpel, scissors, saw, drill, thread cutting tool, centering tool, drill-jig bushing, or as templet.

36. A tool made of biocompatible bioinert material.

37. The tool according to claim 36, wherein the biocompatible bioinert material is high-strength technical ceramic.

38. The tool according to claim 36, wherein the biocompatible bioinert material is a ceramic on an aluminum oxide, zirconium oxide or silicon nitride basis.

39. The tool according to claim 36, wherein the biocompatible bioinert material is a Y-TZP or ZTPA ceramic.

40. The tool according to claim 36, wherein the tool is formed as a scalpel, scissors, saw, drill, thread cutting tool, centering tool, drill-jig bushing or as a templet.

41. The tool according to claim 36, wherein at least a portion of the surface consists of the biocompatible bioinert material.

REMARKS

Applicants respectfully request entry of the foregoing amendment. Early and favorable action on the pending Claims is earnestly solicited. If any fees are due to maintain pendency of this application, authorization is granted to charge such fees to Deposit Account No. 50-0624.

Respectfully submitted,

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Medical Instruments

The subject of the present invention is medical instruments, and methods for their manufacture, as well as the use thereof.

Recent studies on patients with implants/prostheses have shown that in the postprosthetic tissue traces of iron could be detected. This finding is surprising insofar as iron could be detected even when implants/prostheses of absolutely iron-free materials have been used and the explanation of the implants/prostheses and the analysis of the periprosthetic tissue was performed with iron-free research instruments. Even in the case of explantates made of absolutely iron-free materials – for example even in the case of titanium prostheses – iron was detected by such studies in the periprosthetic tissue in amounts of up to 1 mg/g of tissue.

The induction effect of iron on fibroblasts, for example, is known. About 30% of the so-called "exchange operations" are made necessary predominantly by particles in the periprosthetic tissue which are responsible for the loosening of implants/prostheses ("particle disease"). Iron, on the one hand an essentially necessary element for the organism, on the other hand exercises evidently massive deleterious effects in the environment of implants/prostheses, e.g., on the ingrowth performance of osteosynthesis plates, implants, prostheses, screws, etc.

Results obtained on the basis of the use – due to the special research methodology – of absolutely iron-free instruments, the iron detected in the periprosthetic tissue of iron-free implants/prostheses must consequently have insinuated themselves during the operation.

Many operational techniques in orthopedics or surgery call for the use of scalpels, scissors, saws, drills, thread cutting tools, centering tools, bushings, templets and other such instruments made of materials containing iron. Consider here, for example, the article, "Semiconstrained Total Elbow Replacement for the Treatment of Post-Traumatic Osteoarthrosis" by A.G. Schneeberger et al., The Journal of Bone and Joint Surgery, Vol. 79-A, No. 8, August 1997, p. 1211 ff.

Surprisingly, in studies of these instruments after their use, definite traces of wear were found. Wear results from the attrition of the ferrous material and sometimes can be seen with the naked eye. This iron-containing detritus created during the operation evidently collects in the periprosthetic tissue and thus can be blamed at least partially for the loosening of the prostheses.

The present invention was therefore aimed at reliably preventing detritus of iron particles from forming in operations.

It was therefore one objective of the invention to make available tools and instruments which, when used in surgical operations, for example in the cutting of bone and in the insertion of implants, will produce no iron particles, in order thus to keep osteolytically active iron out of the tissues.

The problem to which the present invention is addressed was attained according to the invention by the use of biocompatible bioinert materials for the manufacture of medical/surgical instruments and by the use of medical/surgical instruments made from biocompatible bioinert materials in surgical operations.

According to the invention, medical/surgical instruments are prepared from biocompatible bioinert materials.

The use of biocompatible bioinert materials is of decisive importance for the solution according to the invention. Such biocompatible bioinert materials include ceramics. Examples to mention here are high-strength technical ceramics, such as those on a basis of aluminum oxide, zirconium oxide or silicon nitride. Especially preferred are so-called Y-TZP ceramics or also ZPTA ceramics. ZPTA ceramics consist of a matrix material which is composed of an aluminum oxide/chromium oxide mixed crystal and is platelet-reinforced *in situ*. Such ceramics are described for example in EPA 0 542 815. These are ceramics in which zirconium dioxide containing stabilizing oxides is embedded in a matrix material of a sintered body formed of an aluminum oxide / chromium dioxide mixed crystal, the amount of the stabilizing oxides being so chosen that the zirconium dioxide is predominantly tetragonal. In addition to these ceramics, however, other ceramics can also be used. It must only be assured that they are biocompatible and bioinert. Such ceramics have long been known in medical technology. They include, among other things, the ceramics from which implants are made, for example, and which are sold by the applicant under the names Biolox® and Ziolox®.

From these high-strength technical ceramics scalpels, scissors, saws, drills, thread cutting tools and centering tools, drill-jig bushings, templets and other such instruments can be made.

The production of the ceramics needed for these instruments is performed in a manner

known to the practitioner of the art. It is to be noted, however, that the ceramic required for these instruments must be sharp-edged for use according to the invention in medicine or surgery, and must contain no phase of the kind used in ceramics for cutting metal.

A drill according to the invention is obtained, for example, by first producing a cylinder, from a ceramic according to EPA 0 542 815, for example, into which the shape necessary for use as a cutting instrument is ground. Figure 1 shows drills which were made in this manner. Likewise possible is the production of a ceramic close to final shape by injection molding methods or by the so-called DCC method, which is then finished accordingly. In the DCC method the green body is made directly from the suspension. For this purpose the ceramic mixture with a solid content of more than 50 vol.-% is ground in an aqueous suspension. The pH value of the mixture is then to be adjusted to 4 - 4.5. After grinding, urea and a quantity of the enzyme urease is added, which is able to degrade the urea before this suspension is poured into a mold. The enzyme-catalyzed degradation of the urea shifts the pH of the suspension toward 9, while the suspension coagulates. The green body thus prepared is dried and sintered after removal from the mold. The sintering process can be performed without pressure, but pre-sintering followed by hot isostatic compression is also possible. Further details on this process (DCC process) are disclosed in WO 94/02429 and in WO 94/24064, to which reference is expressly made.

A scalpel according to the invention or a scissors according to the invention can be obtained basically according to DE 43 13 305, for example, while the cutting blades of the scissors according to the invention can have either different hardnesses or the same

hardness.

According to the invention it is likewise possible to coat known medical/surgical instruments with biocompatible bioinert materials.

In all cases, the appearance, the shape, the geometry, the size of the medical/surgical instruments of the invention can correspond to the medical/surgical instruments used heretofore.

By the use according to the invention of biocompatible bioinert materials for the production of medical/surgical instruments or the use of the medical/surgical instruments consisting of biocompatible bioinert materials in surgical operations it is thus possible for the first time reliably to avoid the entry of iron-containing particles into the tissue. The medical/surgical instruments according to the invention can therefore be used in operations, for example, to avoid the production of any osteolytically active ferrous particles due to the cutting of bone.

The medical/surgical instruments according to the invention have an extremely great resistance to wear and accordingly high mechanical qualities. It is furthermore advantageous that the cutting characteristic of the medical/surgical instruments according to the invention is substantially better than the cutting characteristic of conventional instruments of the same geometry. Figure 2 shows the comparison between a conventional drill of metal and a drill according to the invention made of biocompatible bioinert ceramic when used in bone. One reason for this is the surface of the ceramics used according to the invention. Whereas in the case of conventional medical/surgical instruments wettability

problems are known to occur when fatty tissue is cut – fatty tissue dulls conventional scalpels, a reason why by now scalpels are used as single-use instruments – this problem does not occur with the medical/surgical instruments according to the invention.

Due to the better cutting characteristic of the medical/surgical instruments of the invention better performance can generally be assumed. Table 1 and Figure 3 show the comparison of two drills according to the invention with a conventional drill of metal of the same geometry when used in bone.

Of especial, particularly economical importance is furthermore the possibility of being able to use the medical/surgical instruments of the invention more often than once. Conventional instruments of metal can and are, as a rule, used only once. On account of their surface chemistry the medical/surgical instruments of the invention can also be re-sterilized after use, without problems; even if the medical/surgical instruments according to the invention are autoclaved they are superior in performance to the conventional instruments (cf. Figure 3).

Of especial advantage is furthermore the use of the medical/surgical instruments of the invention in connection with new operation techniques, such as so-called "roboting" or so-called "imaging." For example, the use of nuclear spin tomography in the operating room makes it necessary to use nonmetallic instruments. Whereas images of metallic instruments are blurred in nuclear spin tomography, the medical/surgical instruments of the invention are imaged with sharp contours.

In connection with this invention, when medical/surgical instruments are mentioned,

this is to be understood as including instruments and tools which consist at least in part of biocompatible bioinert materials and are used in medicine/surgery and are intended for the same purpose as the medical/surgical instruments.

Table 1

Drill		Drilling time (sec)	Bone thickness (mm)	Drilling depth/sec (mm/sec)
A	cleaned*)	21	5.3	0.252B
	cleaned*)	17	4.6	0.271
	autoclaved	11	4.7	0.427
	autoclaved	33	6.8	0.206
B	cleaned*)	37	6.7	0.154
	cleaned*)	30	6.7	0.158
	autoclaved	40	6.5	0.163
	autoclaves	35	5.6	0.157
Metal		90	7.0	0.084
		67	7.0	0.101

*) with protein-dissolving cleaning agent

Claims

1. Medical/surgical instrument made of biocompatible bioinert material.

2. Medical/surgical instrument characterized in that it is coated with biocompatible bioinert material.

3. Medical/surgical instrument according to claim 1 or 2, characterized in that the biocompatible bioinert material is high-strength technical ceramic.

4. Medical/surgical instrument according to claim 1 or 2, characterized in that the biocompatible bioinert material is a ceramic on an aluminum oxide, zirconium oxide or silicon nitride basis.

5. Medical/surgical instrument according to claim 1 or 2, characterized in that the biocompatible bioinert material is a Y-TZP or ZTPA ceramic.

6. Medical/surgical instrument according to one or more of claims 1 to 5, characterized in that it is formed as scalpel, scissors, saw, drill, thread cutting tool, centering tool, drill-jig bushing, or as templet.

7. Use of a biocompatible bioinert material for the manufacture of Medical/surgical instruments.

8. Use of a biocompatible bioinert material for the manufacture of Medical/surgical instruments, characterized in that the biocompatible bioinert material is a high-strength technical ceramic.

9. Use of a biocompatible bioinert material for the manufacture of Medical/surgical instruments, characterized in that the biocompatible bioinert material is a ceramic on an aluminum oxide, zirconium oxide or silicon nitride basis.

10. Use of a biocompatible bioinert material for the manufacture of Medical/surgical instruments, characterized in that the biocompatible bioinert material is a Y-TZP or ZTPA ceramic.

11. Use of a biocompatible bioinert material for the manufacture of Medical/surgical instruments, characterized in that the biocompatible bioinert material is characterized according to one of claims 3 to 5, and the instrument is made as a scalpel, scissors, saw, drill, thread cutting tool, centering tool, drill-jig bushing or as a templet.

12. Use of a biocompatible bioinert material for coating Medical/surgical instruments.

13. Use of a biocompatible bioinert material for the coating of Medical/surgical instruments, characterized in that the biocompatible bioinert material is a high-strength technical ceramic.

14. Use of a biocompatible bioinert material for the coating of Medical/surgical instruments, characterized in that the biocompatible bioinert material is a ceramic on an aluminum oxide, zirconium oxide or silicon nitride basis.

15. Use of a biocompatible bioinert material for the coating of Medical/surgical instruments, characterized in that the biocompatible bioinert material is a Y-TZP or ZTPA ceramic.

16. Use of a biocompatible bioinert material for the coating of Medical/surgical instruments, characterized in that the biocompatible bioinert material is characterized according to any one of claims 3 to 5, and the instrument is formed as a scalpel, scissors, saw, drill, thread cutting tool, centering tool, drill-jig bushing or as a templet.

17. Use of a tool of biocompatible bioinert material in surgery.

18. Use of a tool of biocompatible bioinert material for cutting bone.

19. Use of a tool of biocompatible bioinert material for the machining of bone.

20. Use of a tool of biocompatible bioinert material to avoid osteolytic particles.

21. Use of a tool of biocompatible bioinert material according to any one of claims 17 to 20, characterized in that the biocompatible bioinert material is characterized according to any one of claims 3 to 5.

22. Use of a tool of biocompatible bioinert material according to any one of claims 17 to 20, characterized in that the biocompatible bioinert material is characterized according to any one of claims 3 to 5, and the tool is formed as a scalpel, scissors, saw, drill, thread cutting tool, centering tool, drill-jig bushing or as a templet.

23. Tool made of biocompatible bioinert material for use as a Medical/surgical instrument.

24. Tool according to claim 23, characterized in that the biocompatible bioinert material is high-strength technical ceramic.

25. Tool according to claim 23, characterized in that the biocompatible bioinert material is a ceramic on an aluminum oxide, zirconium oxide or silicon nitride basis.

26. Tool according to claim 23, characterized in that the biocompatible bioinert material is a Y-TZP or ZTPA ceramic.

27. Tool according to any one of claims 23 to 26, characterized in that the tool is formed as a scalpel, scissors, saw, drill, thread cutting tool, centering tool, drill-jig bushing or as a templet.

28. Tool according to any one of claims 23 to 27, characterized in that at least a portion of the surface consists of the biocompatible bioinert material.

29. Use of a tool made of biocompatible bioinert material in "roboting" or "imaging".

PCT

WELTORGANISATION FÜR GEISTIGES EIGENTUM
Internationales Büro

INTERNATIONALE ANMELDUNG VERÖFFENTLICHT NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT)

(51) **Internationale Patentklassifikation** 7 :
C04B 35/01, A61B 17/16, 17/32

A1

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199 16 149.6 11. April 1999 (11.04.99) DE

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(74) **Anwälte:** UPPENA, Franz usw.; Dynamit Nobel Aktiengesellschaft, Patentabteilung, D–53839 Troisdorf (DE).

(81) **Bestimmungsstaaten:** AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO Patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), eurasisches Patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), europäisches Patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI Patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Veröffentlicht
Mit internationalem Recherchenbericht.
Vor Ablauf der für Änderungen der Ansprüche zugelassenen Frist; Veröffentlichung wird wiederholt falls Änderungen eintreffen.

(54) **Title:** MEDICAL INSTRUMENTS

(54) **Bezeichnung:** MEDIZINISCHE INSTRUMENTE

(57) **Abstract**

The present invention relates to the use of biocompatible and bioinert materials for producing medical/surgical instruments. The invention also relates to medical/surgical instruments made of biocompatible and bioinert materials. The invention further relates to tools made of biocompatible and bioinert materials for the use as medical/surgical instruments. The invention also relates to the use of tools made of biocompatible and bioinert materials in surgery.

(57) **Zusammenfassung**

Die vorliegende Erfindung betrifft die Verwendung biokompatibler bioinerter Materialien zur Herstellung von medizinischen/chirurgischen Instrumenten, medizinische/chirurgische Instrumente aus biokompatiblen bioinerten Materialien, Werkzeuge aus biokompatiblem bioinertem Material zur Verwendung als medizinische/chirurgische Instruments sowie die Verwendung von Werkzeugen aus biokompatiblen bioinerten Materialien in der Chirurgie.

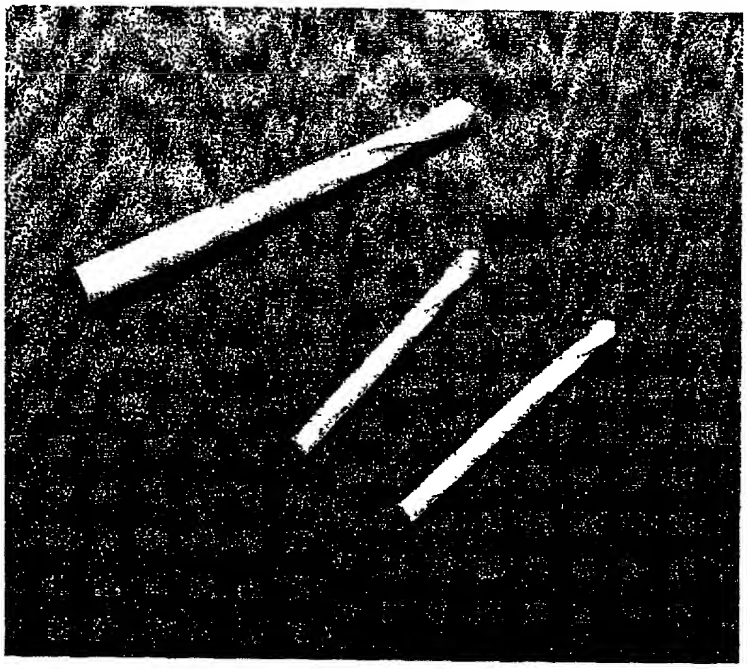
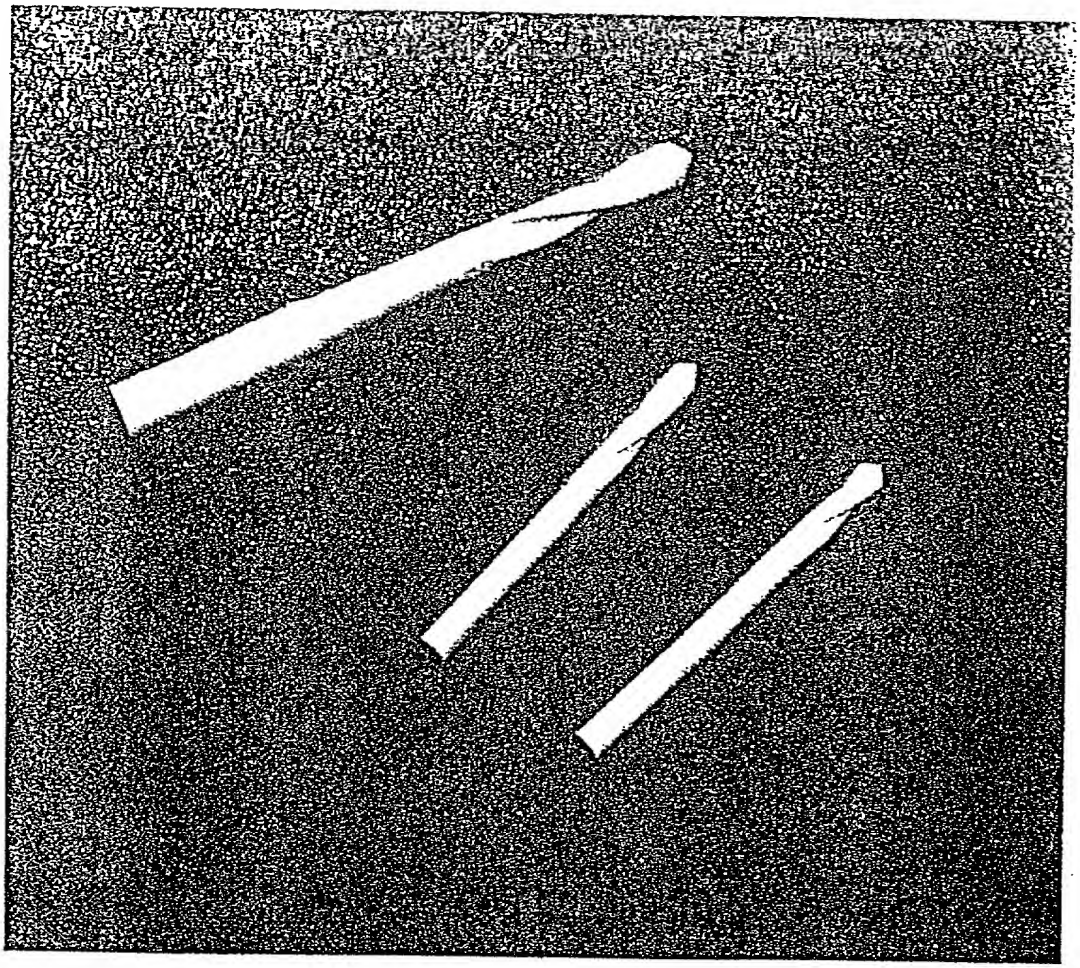
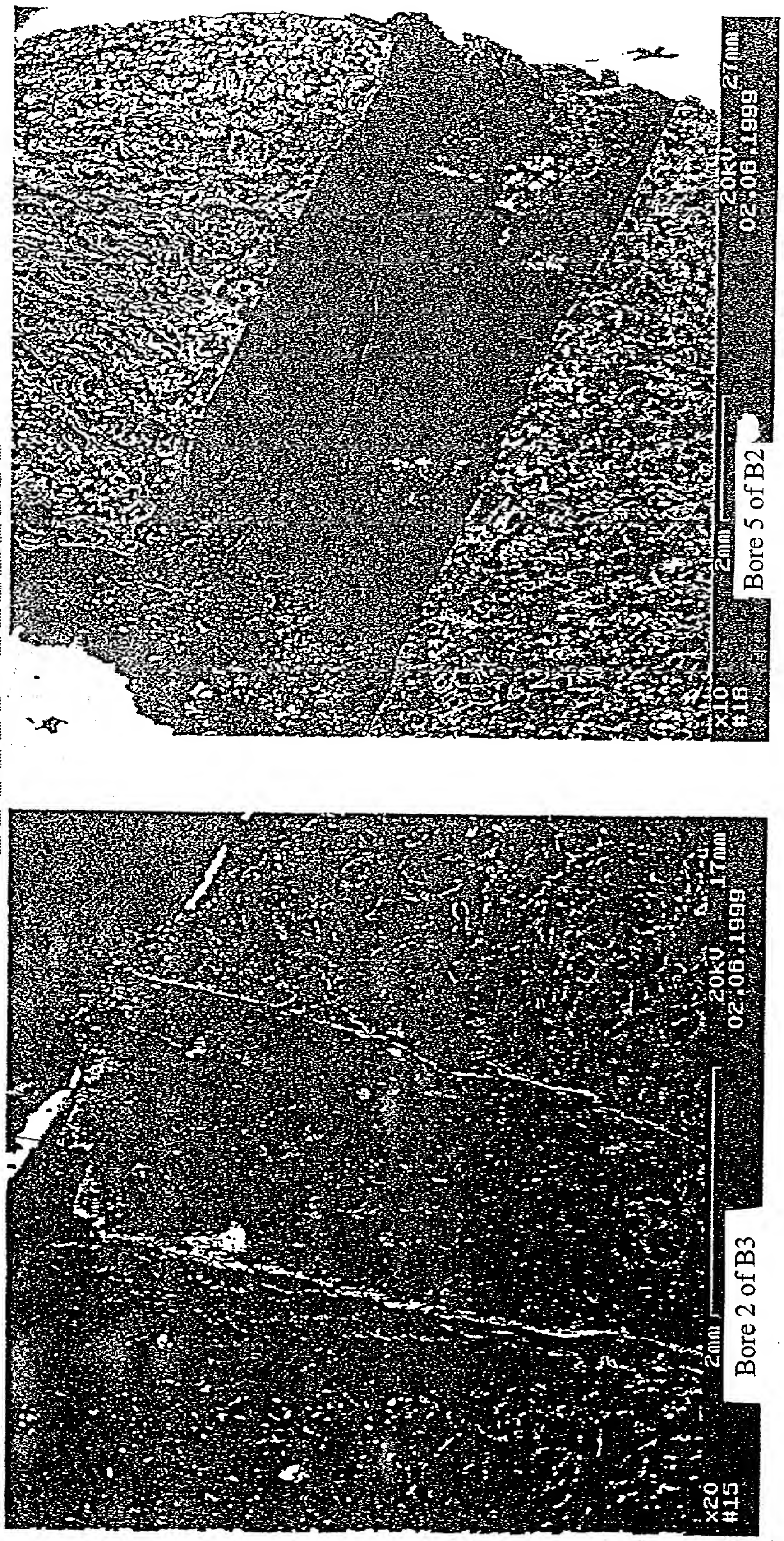


FIGURE 1



09-937,722

FIGURE 2



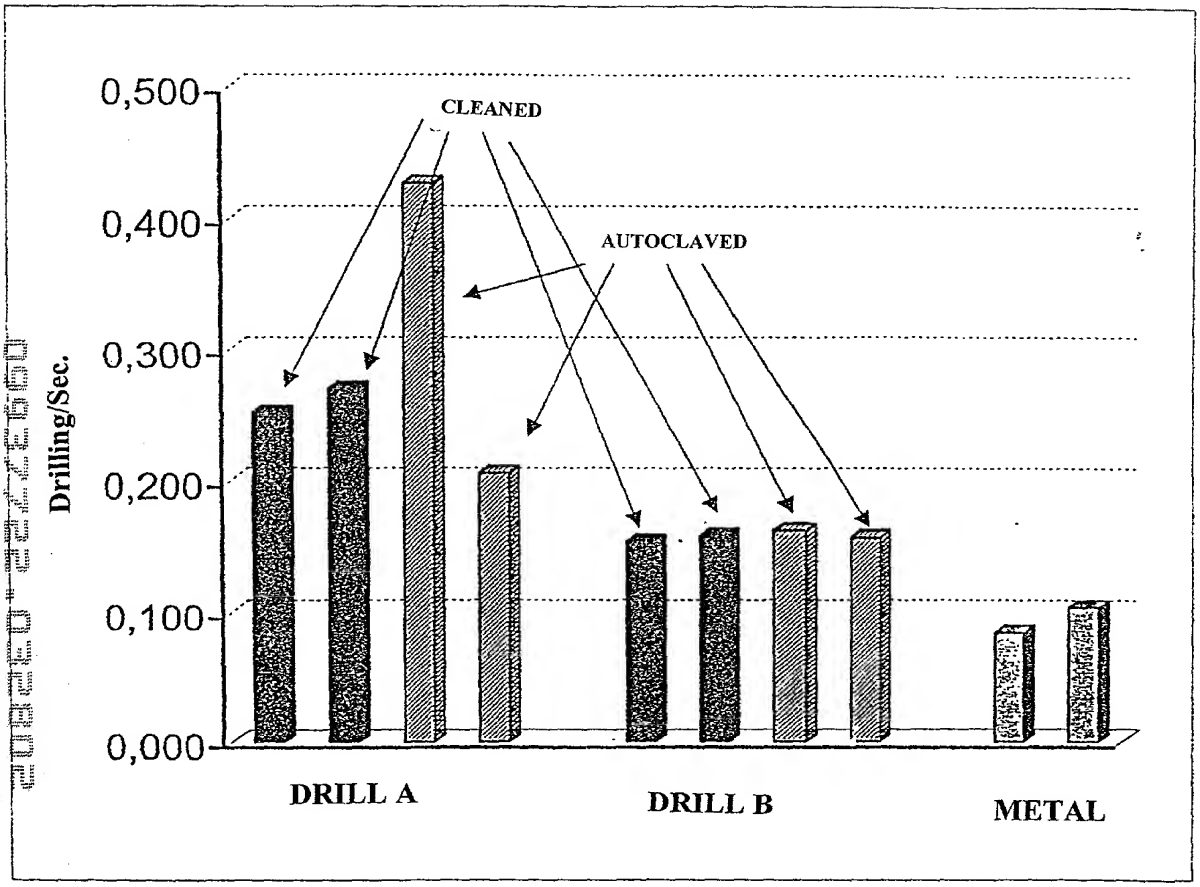
DRILL OF THE INVENTION

MADE OF BIOCOMPATIBLE, BIOINERT MATERIAL

CONVENTIONAL METAL DRILL

09-937,722

FIGURE 3



Docket No.
CERA 233 (10108725)

Declaration and Power of Attorney for Patent Application
English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

MEDICAL INSTRUMENTS

the specification of which (check one)

☐ is attached hereto.

☒ was filed on September 28, 2001 as U. S. Serial No. 09/937,722
as United States Application No. or PCT International Application No.
and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign applications(s) for patent or inventor's certificate, or Section 365(a) of any PCT international application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

			Priority Not Claimed
199 16 149.6 (Number)	DE (Country)	April 11, 1999 (Filing Date)	☐
(Number)	(Country)	(Filing Date)	☐
(Number)	(Country)	(Filing Date)	☐

PATENT Docket No.
Serial No.

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)

I hereby claim the benefit under 35 U.S.C. Section 120 of any United States application(s), or Section 365(c) of any PCT international application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, CFR, Section 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
PCT/EP00/03240	April 11, 2000	Pending
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

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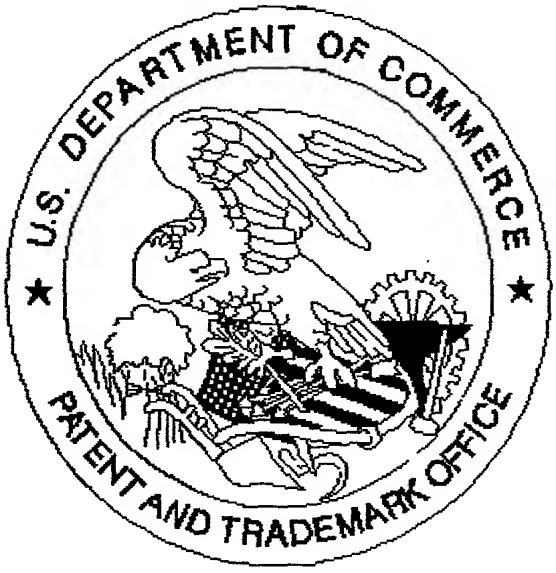

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